K021775
PG. 1 OF 1

PREMARKET NOTIFICATION 510(K) SUMMARY

DEC 23 2002

Applicant: HealthTronics Surgical Services, Inc.
1841 West Oak Parkway
Marietta, Georgia 30062
Telephone: 770-419-0691
Facsimile: 770-419-9490

Manufacturer: HMT High Medical Technologies, AG
Lengwil, Switzerland

Official Contact: Peter Weiman
Manager of Clinical Programs
HealthTronics Surgical Services, Inc.

The LithoDiamond is indicated for use in patients with renal and upper ureteral calculi between 4m and 20mm in size.

This device is substantially equivalent to the predicate device, the LithoTron (P970019), also manufactured by HMT. The primary difference in the devices is that the LithoDiamond has a new imaging system.

The equivalence argument in the 510(k) was supported by bench data (as outlined in FDA's "Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi." (August 9, 2000)). Detailed shock wave characteristics as well as safety data were presented in the 510(k). An initial report on the imaging system (x-ray component) is also on file at FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 2002

Mr. Peter Weiman
Manager of Clinical Programs
HealthTronics, Inc.
1841 West Oak Parkway
MARIETTA GA 30062

Re: K021775
Trade/Device Name: HealthTronics LithoDiamond (ESWL) Lithotripter (LTF0230)
Regulation Number: 21 CFR §876.5990
Regulation Name: Extracorporeal shock wave lithotripter
Regulatory Class: II
Product Code: 78 LNS
Dated: September 25, 2002
Received: September 27, 2002

Dear Mr. Weiman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K021775

Device Name: LithoDiamond

Indications for Use:

The LithoDiamond is indicated for use in patients with renal and upper ureteral calculi between 4mm and 20mm in size.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Device ✓

David A. Feigal

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021775